K000685

AUG 1 5 2000

SECTION 1.0 – 510(k) SUMMARY
CHARTER MEDICAL, Ltd.
Neonatal Syringe Set

January 3, 2000

Applicant

Name	Charter Medical, Ltd.
Address	1805 Swarthmore Avenue Lakewood, NJ 08701

Contact Person Lisa Krallis-Nixon
President and General Manager

Telephone	732.901.9400
FAX	732.901.9401

Submission Correspondent K. Alice Preville

Telephone	732.775.0363
FAX	732.901.9401

Device Nomenclature

Trade Name	Charter Medical Neonatal Syringe Set
Common Name	Fluid reservoir and delivery system
Classification Name	A device used to administer fluids from a container to a patient's vascular system.
Class II	21 CFR 880.5440
Panel	80
Procode	~~FRA~~ BRZ

Predicate Device

Pediatric Transfer Bag	Charter Medical Ltd.	510(k) BK960043
Piston Syringe	Becton Dickinson	Preamendment 510(k) K942615 510(k) K980987

Device Description Transfer tubing assembly with an in-line 150 micron screen mesh filter assembled to a purchased piston syringe.

Intended Use To facilitate apportionment and delivery of small aliquots of whole blood, cellular (red cells and platelets) and non-cellular components (fresh frozen plasma and cryoprecipitate).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2000

Mr. Kenneth Finch
Charter Medical, Limited
3948-A West Point Boulevard
Winston Salem, North Carolina 27103

Re: K000685
Trade Name: Charter Medical Neonatal Syringe Set
Regulatory Class: II and II
Product Code: BRZ and FMF
Dated: July 5, 2000
Received: July 11, 2000

Dear Mr. Finch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000685

510(k) Number (if known): K000685

Device Name: Charter Medical Neonatal Syringe Set

Indications for Use: Intended to facilitate apportionment and delivery of small aliquots of whole blood, cellular (red cells and platelets) components and non-cellular (fresh frozen plasma and cryoprecipitate) components for neonatal/pediatric transfusion.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ~~ANOTHER PAGE IF~~ NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucuzzella

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000685